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September 4, 2008

BY E-FILING

The Honorable Mary Pat Thyng
United States District Court
for the District of Delaware
844 King Street
Wilmington, DE 19801

Re: *Roquette Frères v. SPI Pharma, Inc., et al.*
C.A. 06-540 (GMS/MPT)

Dear Magistrate Judge Thyng:

In its letter of September 3, 2008 prior to tomorrow's teleconference, SPI mischaracterizes the substance and purpose of Dr. Brittain's August 5 test. SPI incorrectly asserts that Dr. Brittain's test "showed a non-infringing friability result," in an attempt to obtain further discovery of information it has long been aware of. The test was performed subsequent to receipt of SPI's expert reports in order to demonstrate that the friability values SPI's expert witnesses rely upon were the result of incorrect testing by SPI.

Contrary to the patent, SPI measured friability of its products using a tablet drum. On August 5, in reaction to statements made in SPI's expert rebuttal reports which contend that SPI's different friability measurements were the result of variations in sieving, Dr. Brittain performed SPI's incorrect friability test to show that SPI's different and inaccurate measurements resulted from its use of the wrong drum. The result of that test, which Roquette immediately produced, is unrelated to infringement because it does not perform the friability test required by the claims of the patent.

Well before the end of discovery, Dr. Brittain tested SPI's products for infringement, including measuring friability with an abrasion drum, which Dr. Brittain selected as the appropriate drum called for by the claims of the '777 patent. The details of those tests and the equipment used were identified in his notebook pages and shown in videos, which Roquette produced. The only different piece of equipment used in Dr. Brittain's subsequent test of August 5 was the tablet drum.

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SPI's discovery requests are: (1) irrelevant to any affirmative defense or counterclaim that SPI has raised in this case; (2) cumulative of discovery already produced; (3) made only after the close of discovery; and are essentially moot. Accordingly, Roquette requests that SPI's belated demand for further discovery be denied.

(1) Dr. Brittain's Single Tablet Drum Test Is Irrelevant to Any of SPI's Asserted Defenses and Counterclaims in This Case

SPI's contention that Dr. Brittain's tablet drum test showed a "non-infringing friability result" is a mischaracterization of fact. To the contrary, Dr. Brittain confirmed in his deposition that using the tablet drum, as SPI did in its friability measurements, was not the test called for by the '777 patent:

So I don't think one reading this [the '777 patent] would think of using a tablet drum. I think they would be led to use an abrasion drum. (Brittain Dep. at 18:12-14, Exh. A hereto).

All of Dr. Brittain's infringement-related friability tests were conducted with an abrasion drum, which Dr. Brittain selected as the appropriate drum called for by the claims of the '777 patent and which he identified in his notebook pages, videos and initial expert report.

Thus, Dr. Brittain's subsequent tablet drum test intentionally was not the friability test ("Test I") recited in the claims of the '777 patent. Nor did Dr. Brittain conduct that test for any purpose related to his infringement analysis. Rather, Dr. Brittain explained that he conducted that test "[i]n response to some of the things I had read in [SPI's expert] rebuttal reports." (Brittain Dep. at 8:3-8, Exh. A hereto). SPI's expert rebuttal reports contend that the difference between SPI's and Dr. Brittain's measured friability values was caused by variations in sieving. Dr. Brittain then conducted the tablet drum test on August 5 to determine whether SPI's different measured friability value instead was caused by SPI's use of the wrong drum. Roquette produced Dr. Brittain's notebook pages relating to that tablet drum test three days later at the beginning of his deposition.

Contrary to SPI's suggestion made in the third bullet point on page 2 of its letter, SPI has **never** raised any question as to which drum should be used in the friability test in support of any claim of invalidity, nor has it raised that point in any interrogatory response, invalidity contention or expert report or expert testimony. Rather, as noted above, SPI's non-prior art invalidity defense has been directed exclusively to sieving.

(2) Roquette Has Produced Information That Identifies and Depicts All of the Equipment Used by Dr. Brittain in His Infringement Tests

The equipment used by Dr. Brittain in his infringement tests is identified and depicted in the documents and videos which Roquette produced more than four months ago. That equipment also is commercially available, if not already owned by SPI. Any physical inspection of such equipment would be cumulative to what has already been produced.

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Both of SPI's technical experts, Drs. Masters and Davé, were able to opine in their rebuttal reports regarding SPI's friability data without ever inspecting or even viewing SPI's equipment. (See Masters Dep. at 41:12-15 and Davé Dep. at 78:8-79:1, Exhs B and C hereto) (indicating that neither expert has ever seen an ERWEKA friability device). SPI offers no reason why it now needs to inspect Dr. Brittain's equipment, which in any event has already been fully identified in writing and depicted in video.

(3) SPI's Requests for Information It Knew of Well Before Discovery Closed, But Requested Only After Discovery Closed, are Untimely

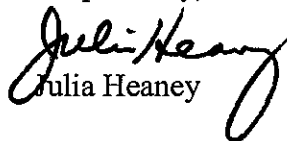
Discovery ended June 30, 2008. (D.I. 187). More than a month later, SPI made new discovery requests regarding Dr. Brittain's laboratory equipment. (SPI's Exh. A).

Prior to the close of discovery, SPI knew of each piece of equipment that Dr. Brittain used in conducting his tests pertaining to his opinion of infringement. Dr. Brittain's equipment was identified in his notebook pages, and shown in videos, each of which were produced to SPI on April 17, 2008.

SPI had ample opportunity to request information regarding that equipment in a timely fashion long before discovery closed and it offers no excuse for its delay.

Although SPI's request is without merit and untimely, Roquette is willing to make available the ERWEKA operating manual and certificates pertaining to the Gilson Ro-Tap device, and to permit inspection of the tablet drum used by Dr. Brittain in the August 5 test at Young and Thompson's Virginia office at a mutually agreeable date and time.

Respectfully,


Julia Heaney

JH:ncf

cc: Dr. Peter Dalleo, Clerk (By hand delivery)
John W. Shaw (By e-mail)
Oren D. Langer (By e-mail)

2474829

EXHIBIT A

HARRY BRITTAIN
BEFORE THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

-----x
ROQUETTE FRERES, :
Plaintiff, : Civil Action No.
vs. : 06-540 (GMS/MPT)
SPI PHARMA, INC., DRYTEC LTD., :
ANHYDRO U.K. LTD., DRYTEC :
CONTRACT PROCESSING LTD., and :
ANHYDRO HOLDING A/S, :
Defendants. :

-----x
VIDEOTAPED DEPOSITION OF HARRY BRITTAIN

Washington, D.C.

Friday, August 8, 2008

REPORTED BY:

SARA A. WICK, RPR, CRR

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1 HARRY BRITTAIN
2 Videotaped deposition of HARRY BRITTAIN, called
3 for examination pursuant to Notice of Deposition, on
4 Friday, August 8, 2008, in Washington, D.C., at the
5 offices of Morgan, Lewis & Bockius LLP, 1111
6 Pennsylvania Avenue Northwest, at 9:37 a.m. before
7 SARA A. WICK, a Notary Public in and for the
8 District of Columbia, when were present on behalf of
9 the respective parties:

10 DOUGLAS V. RIGLER, ESQ.
11 JEFFREY R. SNAY, ESQ.
12 Young & Thompson
13 745 South 23rd Street
14 Arlington, Virginia 22202
15 703-521-2297
16 drigler@young-thompson.com
17 jsnay@young-thompson.com
18 On behalf of Plaintiff
19
20
21
22
23
24 -- continued --
25

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1 HARRY BRITTAIN
2 APPEARANCES (continued):

3 BRIAN P. MURPHY, ESQ.
4 OREN D. LANGER, ESQ.
5 Morgan, Lewis & Bockius LLP
6 101 Park Avenue
7 New York, New York 10178
8 212-309-2108
9 bmurphy@morganlewis.com
10 olanger@morganlewis.com
11 On behalf of Defendant SPI Pharma, Inc.
12
13

14 ALSO PRESENT: Larry Flowers, Video Operator
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1 HARRY BRITTAIN
2 PROCEEDINGS
3 VIDEO OPERATOR: This is the start of tape
4 labeled 1 of the videotaped deposition of Dr. Harry
5 Brittain, in the matter of Roquette Freres, 09:34:56
6 Plaintiff, versus SPI Pharma, Inc., et al.,
7 Defendant, in the United States District Court for
8 the District of Delaware, Civil Action Number 06-540
9 (GMS/MPT).

10 This deposition is being held at Morgan 09:35:15
11 Lewis, 1111 Pennsylvania Avenue Northwest,
12 Washington, D.C., on August 8, 2008, at
13 approximately 9:37 a.m.

14 My name is Larry Flowers from TSG
15 Reporting, Inc., and I am the legal video 09:35:30
16 specialist. The court reporter is Sara Wick, in
17 association with TSG Reporting.

18 Will counsel please introduce yourselves.

19 MR. MURPHY: Yes. Brian Murphy from
20 Morgan, Lewis & Bockius, on behalf of the Defendant 09:35:41
21 SPI Pharma. And with me is Oren Langer, also from
22 Morgan, Lewis.

23 MR. RIGLER: Douglas Rigler and Jeffrey
24 Snay, representing Roquette Freres.

25 VIDEO OPERATOR: And will the court 09:35:58

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1 HARRY BRITTAIN
2 reporter please swear in the witness.
3 Whereupon,

4 HARRY BRITTAIN
5 was called as a witness and, having first been duly
6 sworn, was examined and testified as follows:

7 EXAMINATION

8 BY MR. MURPHY:

9 Q Good morning, Dr. Brittain.

10 A Good morning. 09:36:12

11 Q Dr. Brittain, you've been deposed before;
12 correct?

13 A Yes, I have.

14 Q You understand the procedure; right?

15 A I believe I do. 09:36:19

16 Q You've been retained as an expert for the
17 plaintiff in this case; is that right?

18 A Yes.

19 Q And that's Roquette Freres?

20 A Yes. 09:36:29

21 Q And Roquette Freres is a French company
22 that makes pharmaceutical excipients; right?

23 A That is my understanding.

24 Q And what's your area of expertise or
25 background? 09:36:39

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1 HARRY BRITTAİN

2 A My background is in physical chemistry,
3 physical characterization of solid materials.4 Q All right. Any other areas of expertise
5 that you'd like to put on the record? 09:36:566 A I certainly have expertise in
7 pharmaceutical formulations, characterization of
8 bulk drug substances.9 Q All right. You've been retained as an
10 expert witness by Roquette Freres; right? 09:37:18

11 A Yes, I have.

12 Q And when were you first retained?

13 A I don't remember the exact date.

14 Q Approximate month or year?

15 A Probably some time last year, maybe the 09:37:34
16 middle of the year. I really don't remember the
17 month.

18 Q Some time in 2007?

19 A I believe so.

20 Q And you have submitted two expert reports 09:37:53
21 in this case; is that correct?

22 A Yes, I have.

23 Q And those reports are signed by you;
24 right?

25 A Yes, they are. 09:38:03

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1 HARRY BRITTAİN

2 Q And those two reports reflect all of the
3 opinions that you intend to give in this case at the
4 time of trial; right?5 A Well, they certainly reflect all the 09:38:12
6 opinions I have developed to date. What happens at
7 trial, I have no way of knowing.8 Q But as of today, is it correct that your
9 written reports reflect the opinions that you've
10 developed and intend to give at trial? 09:38:29

11 A As far as I know, yes.

12 Q So there's nothing - if there's something
13 that's not contained in your report, you're not
14 going to give an opinion on it; correct?15 A Not necessarily. Everything depends upon 09:38:44
16 the nature of questions which are posed to me.17 Q Is there anything you're aware of today
18 right now that's not in your report that you would
19 expect to give an opinion on at trial?

20 A It could happen, yes. 09:39:00

21 Q No, I mean specifics. Are you aware of
22 anything right now?23 A Well, I'm aware of one specific, let's
24 say, set of observations that I've made recently.

25 Q And could you, please, describe that for 09:39:15

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1 HARRY BRITTAİN

2 me?

3 A Yes. In response to some of the things I
4 had read in rebuttal reports, last week - no, early
5 this week, in fact, I conducted some additional 09:39:41
6 experimentation because I was rather perplexed by
7 some of the things I had read and learned, something
8 very interesting.

9 Q When did you conduct these experiments?

10 A Monday and Tuesday of this week. 09:40:04

11 Q Did you bring any documents reflecting
12 those experiments with you today?

13 A I haven't brought any documents.

14 Q Have you supplemented any of your reports?

15 A No. 09:40:17

16 Q What was the interesting thing that you
17 learned?18 A Well, I believe I have uncovered the
19 reason why the friability values measured by SPI
20 were so low compared to the friability values I 09:40:37
21 obtained on comparable Mannitol materials.22 Q This information that you just described
23 is not in either of your two expert reports; is that
24 correct?

25 A It is not. 09:40:54

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1 HARRY BRITTAİN

2 Q And you don't have any documents
3 reflecting that work here today, do you?

4 A I don't personally, no.

5 MR. RIGLER: We do. 09:41:03

6 MR. MURPHY: What does that mean?

7 MR. RIGLER: We have the notebook entry
8 for the experiment.

9 MR. MURPHY: Can I have them, please?

10 Let's take a break and go off the record. 09:41:13

11 VIDEO OPERATOR: We're off the record.

12 The time is approximately 9:43 a.m.

13 MR. RIGLER: Let's stay on the record for
14 one minute, please.

15 VIDEO OPERATOR: We're still on. 09:41:28

16 MR. RIGLER: Jeffrey, I'm not sure that
17 these pages have been Bates numbered even. So we
18 might hand Bates number them so that we'll have a
19 record for identification.20 MR. SNAY: It's correct, they have not 09:41:42
21 been Bates numbered, and I can hand-enter them.22 MR. MURPHY: Why don't you give me one
23 while you're entering the others.

24 MR. SNAY: That's fine.

25 MR. MURPHY: Can we go off the record, 09:41:56

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1 HARRY BRITTAIN
 2 then, a copy of your notebook with experiments
 3 entries from this case previously provided by
 4 counsel for Roquette, Bates numbered RF2012 through
 5 RF2037. 09:52:18
 6 (Exhibit 39 identified.)
 7 BY MR. MURPHY:
 8 Q Dr. Brittain, I've handed you now what
 9 we've marked as Defendant's Exhibit 39. Can you,
 10 please, take your time, take a moment to look 09:52:42
 11 through it and confirm that, in fact, this is a copy
 12 of your notebook entries on the experiments that you
 13 performed in this case on SPI Pharma's Mannogem EZ
 14 and Mannitol HS products.
 15 A Yes, yes, this is a copy of my research 09:53:14
 16 notebook.
 17 Q All right. So if you could, let's keep in
 18 front of you both of these exhibits since we now
 19 have the -- all of the entries from your notebook,
 20 at least as of today. And looking at page 1 in 09:53:24
 21 Defendant's Exhibit 39, page 1 of your notebook
 22 Bates numbered RF 2014, at the top, you've
 23 written "material received"; correct?
 24 A Yes.
 25 Q And you reference Mannogem EZ lot 2635-CPC 09:53:47
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1 HARRY BRITTAIN
 2 as the specific lot of Mannogem EZ that you received
 3 for testing; correct?
 4 A That is correct.
 5 Q And you received that material on February 09:54:00
 6 6th, 2008; right?
 7 A Yes.
 8 Q And that's the same material that you used
 9 for your experiment earlier this week on August 5th
 10 of 2008, as reflected in Defendant's Exhibit 38; 09:54:12
 11 right?
 12 A That is correct.
 13 Q Going back to Defendant's Exhibit 39 on
 14 page 1 of your notebook, and we're under the entry
 15 that you made on February 6th, 2008, you've also 09:54:30
 16 pasted a copy of the patent claim on that page;
 17 right?
 18 A Yes, I have.
 19 Q And when I say "patent," I'm referring to
 20 the patent in suit, which is U.S. Patent No. 573777; 09:54:44
 21 right?
 22 A Yes.
 23 Q So you've basically cut and pasted claim 1
 24 from the patent into your notebook; correct?
 25 A That is correct. 09:54:54
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1 HARRY BRITTAIN
 2 Q And you did that as a point of reference
 3 for the tests that you were going to conduct; right?
 4 A Yes.
 5 Q And isn't it correct that claim 1 of the 09:55:01
 6 patent doesn't say anything about an abrasion drum
 7 or a tablet drum?
 8 A It does not have those specific records in
 9 it, no.
 10 Q And in fact, the entire '777 patent does 09:55:12
 11 not have any reference to an abrasion drum or a
 12 tablet drum; right?
 13 A I don't recall it saying those words, no.
 14 Q In fact, it doesn't say anything about the
 15 type of drum to be used for the friability test 09:55:28
 16 anywhere in the '777 patent; right?
 17 A I'm not 100 percent sure. It's possible
 18 that the reference to the TAP friabulator could
 19 contain a reference to the abrasion drum, but I
 20 don't know that for sure. 09:55:48
 21 Q Okay. Let me hand you a copy of the
 22 patent in suit, then, please. I believe it's been
 23 previously marked. Well, we're going to mark it
 24 again. I'll have the reporter mark this as
 25 Defendant's Exhibit 40. 09:56:05
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1 HARRY BRITTAIN
 2 (Exhibit 40 identified.)
 3 BY MR. MURPHY:
 4 Q So Dr. Brittain, you have a copy of the
 5 patent in suit in your hands. We've marked it again 09:56:30
 6 now as Defendant's Exhibit 40. Either you can find
 7 it, or I can try and help you find the reference to
 8 the Erweka TAP friabilimeter. I have it in column
 9 5, if that helps you, if you start about line 22.
 10 A Yes, I see that. 09:56:59
 11 Q Is that what you were referring to in your
 12 previous answer?
 13 A Yes.
 14 Q Take a moment to read that paragraph, and
 15 just tell me when you're finished, please. 09:57:11
 16 A Yes, I'm finished.
 17 Q All right. And isn't it correct that in
 18 that paragraph, there is no reference to any
 19 particular type of drum to be used in the Erweka
 20 friabilimeter? 09:57:43
 21 A I'm not sure about that. It doesn't say
 22 abrasion. It doesn't say tablet drum. But it does
 23 reference something called a crushing chamber. As I
 24 said before, a tablet drum is specifically
 25 engineered, was designed to measure the ability of 09:57:55
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1 HARRY BRITTAIN
2 tablets to be chipped; whereas, the abrasion drum
3 was designed to be a measurement of abrasion.
4 Now, since the test method talks about the
5 introduction of steel balls, there's no doubt that 09:58:14
6 in an abrasion drum through the tumbling there will
7 be abrasion and crushing. I don't -- when I see the
8 word "crushing chamber," it does not bring to mind a
9 tablet drum. I think one reading this would look at
10 that and say, first of all, that there's no mention 09:58:38
11 in here of testing tablets.

12 So I don't think one reading this would
13 think of using a tablet drum. I think they would be
14 led to use an abrasion drum. But it doesn't say the
15 word "abrasion." In that, you're correct. 09:58:56

16 Q What is your basis for saying you think
17 that?

18 A Well, it's my experience working in
19 physical characterization of pharmaceutical solids
20 over the past now it's more than 20 years. 09:59:11

21 Q So your position is that the use of the
22 word "crushing chamber" instructs someone of
23 ordinary skill not to use a tablet drum?

24 A I don't know that it says not to use a
25 tablet drum. I think what it says is that the 09:59:32

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1 HARRY BRITTAIN
2 appropriate drum is an abrasion drum.

3 Q Where does it say that?

4 A It's through the use of the 09:59:41
5 words "crushing chamber" of this what I will call
6 friabulator. It's the American expression.

7 Q So the patent doesn't say that; correct?
8 You're inferring it from the use of the
9 words "crushing chamber"; correct?

10 A Yes. That's what I said earlier. 09:59:53

11 Q What's a Erweka TAP friabilimeter?

12 A Erweka is the company name, and I'm not
13 totally familiar with the nomenclature of their
14 different units. The Erweka instrument is -- it's
15 really just a rotating motor. All friabulators are 10:00:13
16 rotating motors, and the important part of the
17 instrument is the drum.

18 Now, whether TAP is a specific model that
19 they sell or sold with an abrasion drum, that, I
20 don't know. I know Erweka makes all types of 10:00:34
21 different drums, and probably as time evolved,
22 they've made additional ones. There are some
23 models, probably, with a single drum.

24 There's some models that let you perform
25 two measurements at a time. They have dual drums. 10:00:48

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1 HARRY BRITTAIN
2 There are other models -- I'm not sure Erweka makes
3 them -- where you can actually stack multiple drums
4 on the same spindle. All of these would have,
5 perhaps, different nomenclatures. 10:00:59

6 Q Have you ever tried to find an Erweka TAP
7 friabilimeter?

8 A I looked on their current Web site once,
9 and the TAP is not listed on their current Web site.

10 Q And the fact is, there is no such thing as 10:01:16
11 an Erweka TAP friabilimeter; correct?

12 A I don't know that, no.

13 Q You've never heard of one before, have
14 you?

15 A I've not been able to -- well, I only 10:01:24
16 looked at the current Web site that Erweka has. I
17 don't know at the time of this patent -- it was
18 issued -- it was filed in 1994. I don't know what
19 Erweka actually sold in 1994. For all I know, they
20 could have had a TAP. It seems to me if the authors 10:01:46
21 of the patent wrote "Erweka TAP," they must have had
22 a Erweka TAP.

23 Q So you're completely speculating on that;
24 correct?

25 A I don't think it's speculation. It's in 10:02:02

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1 HARRY BRITTAIN
2 the patent specification.

3 Q Oh, really? Have you spoken to the
4 inventors?

5 A No. 10:02:08

6 Q Have you read their depositions?

7 A I'm trying to -- I'm not sure. I might
8 have, but I'm not sure.

9 Q Let me ask you, in this case, you've been
10 retained as an expert; is that right? 10:02:32

11 A Yes.

12 Q Have you been provided with the
13 depositions of the inventors?

14 A I think I have. That's what I'm trying to
15 remember. 10:02:39

16 Q Have you been provided with depositions of
17 anyone else besides the two inventors?

18 A Yes, I have.

19 Q And so are you aware of any evidence that
20 suggests that the inventors actually had available 10:02:50
21 to them at the time of this patent application
22 something called an Erweka TAP friabilimeter?

23 A I haven't seen such evidence, no.

24 Q Because no evidence exists to your
25 knowledge; correct? 10:03:06

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EXHIBIT B

FILED SEPARATELY
UNDER SEAL

EXHIBIT C

FILED SEPARATELY
UNDER SEAL